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We claim:

1. A flow regulator implantable within a subject for regulating flow of a drug through a delivery pathway from a source to a treatment site, the flow regulator comprising:

5 a movable diversion member operably coupled to the delivery pathway;
an actuator actuatable to move the diversion member between at least a first mode position and a second mode position;

the first mode position being defined where the diversion member is substantially restricting flow through the delivery pathway;

10 the second mode position being defined where the diversion member is positioned to allow flow through the delivery pathway,

wherein the diversion member is biased to normally return to the first mode position and restrict flow to the treatment site, and wherein supplying power to actuate the actuator moves the diversion member from the first mode position toward
15 the second mode position.

2. The flow regulator of claim 1, wherein an accumulation chamber is defined upstream of the diversion member, and wherein when the diversion member is in the first mode position, a reserve of drug can be accumulated in the accumulation
20 chamber from drug flowing from the source to the regulator.

3. The flow regulator of claim 1, wherein moving the diversion member from a first mode position to a second mode position causes flow through the delivery pathway from a reserve of drug accumulated within the flow regulator.
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4. The flow regulator of claim 1, wherein the delivery pathway includes a delivery conduit with a resilient portion and the diversion member is

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movable to deform the resilient portion such that flow through the resilient portion is restricted.

5 5. The flow regulator of claim 1, wherein the diversion member is movable in a direction substantially perpendicular to a direction of flow through the delivery pathway.

10 6. The flow regulator of claim 4, wherein the diversion member has a first end movable into contact with the resilient portion and an opposite second end, the flow regulator further comprising a spring positioned adjacent the second end to bias the diversion member toward the first mode position.

15 7. The flow regulator of claim 4, wherein a portion of the diversion member that contacts the resilient portion is rounded, and the diversion member in the first mode position pinches off the resilient portion.

20 8. The flow regulator of claim 1, wherein the delivery pathway includes at least a delivery conduit first portion and a delivery conduit second portion, the second portion being made of a resilient material and having an upstream end positioned to overlap a downstream end of the first portion, and wherein the upstream end of the second portion is deformable from pressure within the second portion such that the upstream end can separate from the downstream end of the first portion and allows fluid from within the second portion to escape.

25 9. The flow regulator of claim 1, wherein the diversion element has a spheroidal shape.

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10. A flow regulator implantable within a subject for regulating flow of a drug through a delivery pathway from a source to a treatment site within the subject, the flow regulator comprising:

5 a generally cylindrical body in which a generally axial bore is defined;
the bore having a generally transverse opening defined therein;

a delivery conduit that forms a part of the delivery pathway and extends through the bore, the delivery conduit having a resilient portion positioned adjacent the opening in the bore;

10 a spheroidal diversion element positioned within the opening and adjacent the resilient portion;

a movable member coupled to the body adjacent the diversion element and the opening in the bore and moveable in the axial direction to change the position of the diversion element among at least first and second positions;

15 the first position being defined where the diversion element is urged radially inwardly against the resilient portion and delivery pathway is restricted;

the second position being defined at a point axially spaced from the first position where the diversion element is free to move radially away from the resilient portion such that flow can pass through the delivery conduit; and

20 an actuator positioned within the body and actuatable to move the movable member from the first position in the axial direction.

11. The flow regulator of claim 10, wherein the resilient portion of the delivery conduit is a second portion, and the delivery conduit includes a first portion inserted into an upstream end of the second portion, the delivery conduit having an
25 overlapped region in which the second portion overlaps the first portion in the axial direction.

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12. The flow regulator of claim 11, wherein the first portion has a side wall in which a transverse outlet opening is defined within the overlapped region.

5 13. The flow regulator of claim 12, wherein an accumulation chamber is defined by a space within the delivery conduit from the outlet opening in the first portion downstream to an area where the diversion member contacts the delivery conduit when the movable member is in the first position.

10 14. The flow regulator of claim 13, wherein a diversion pathway is defined from within the first portion, through the outlet opening in the first portion and between the first portion and the second portion.

15 15. The flow regulator of claim 14, further comprising a radially offset outlet tube extending from the body, and wherein the diversion pathway between the first portion and the second portion continues in a downstream direction through the outlet tube.

20 16. The flow regulator of claim 10, wherein the movable member has a generally axial opening dimensioned to receive the body.

17. The flow regulator of claim 10, wherein the movable member is ring-shaped with a generally axial opening dimensioned to slidingly engage an outer side of the body.

25 18. The flow regulator of claim 10, wherein the movable member is spring-biased toward the first position.

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19. The flow regulator of claim 18, further comprising at least one helical spring positioned to urge the movable member toward the first position.

5 20. The flow regulator of claim 10, wherein the body includes a stop portion adjacent the transverse opening, and the movable member contacts the stop member when the movable member is in the first position.

10 21. The flow regulator of claim 10, wherein the body includes a fixed inner part and a fixed outer part that surrounds the inner part, and wherein the fixed outer part houses the actuator and is positioned axially opposite the movable member.

15 22. The flow regulator of claim 10, wherein the actuator is a solenoid that generates a magnetic field when actuated, and wherein the movable ring is made of a ferromagnetic material.

23. The flow regulator of claim 10, wherein the resilient portion is made of a silicone material.

20 24. The flow regulator of claim 10, wherein the delivery pathway includes a delivery outlet tube connected to a downstream end of the resilient portion and extending through an end of the body.

25 25. The flow regulator of claim 10, wherein an axial distance between the first and second positions is less than about 1 mm.

26. An implantable drug delivery system for delivering drug to a treatment site within a subject according to a predetermined treatment plan, comprising:

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an implantable drug source capable of supplying drug at a substantially constant rate;

an implantable flow regulator that is connectable to the source to receive drug from the source;

5 an accumulation chamber defined in the flow regulator and sized to hold a reserve of drug received from the source;

a first outlet on the flow regulator defining part of a diversion pathway along which drug can be diverted to a waste vessel or into systemic absorption;

10 a second outlet on the flow regulator defining part of the delivery pathway to the treatment sites;

the flow regulator having a first mode of operation in which the accumulation chamber is filled and thereafter drug is diverted through the first outlet and along the diversion pathway, and a second mode in which drug flows from the accumulation chamber outward through the second outlet and along the delivery
15 pathway.

27. The implantable drug delivery system of claim 26, wherein in the second mode, drug flow from the accumulation chamber flows at a substantially constant rate through the second outlet.

28. A method of supplying drug on demand in an implantable drug delivery system, comprising:

providing a drug delivery source implanted within a subject containing drug to be delivered to a treatment site;

25 providing a flow regulator implanted within a subject in fluid communication with and positioned downstream of the source, the regulator having an accumulation space defined therein in which a reserve of drug from the source is accumulated, the regulator having a first mode position in which drug from the source is

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diverted away from the treatment site and a second mode position in which drug is delivered to the treatment site; and

supplying drug to the treatment site on demand from the accumulation space after the regulator is changed from the first mode position to the second mode position.

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29. The method of claim 28, further comprising regulating the volume of drug in accumulation space by diverting drug along a diversion path when the accumulation space is filled to a predetermined capacity.